

We claim:

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1. A flash-melt pharmaceutical dosage form comprising a medicament, a superdisintegrant, a dispersing agent and a binder wherein said medicament is aripiprazole, entecavir, cefprozil, pravastatin, captopril, gatifloxacin, desquinolone, omapatrilat or irbesartan and wherein said dispersing agent is calcium silicate, magnesium trisilicate or silicic acid.
  - 10 *gel*  
*AI*  
2. A flash-melt pharmaceutical dosage form according to claim 1 wherein said dispersing agent is calcium silicate.
  - 15 3. A flash-melt pharmaceutical dosage form according to claim 2 wherein said dispersing agent comprises from about 20 to about 70 percent by weight of said dispersing agent based on the total weight of said dosage form.
  - 20 4. A flash-melt pharmaceutical dosage form according to claim 2 wherein said dispersing agent comprises from about 35 to about 45 percent by weight of said dispersing agent based on the total weight of said dosage form.
  5. A flash-melt pharmaceutical dosage form according to claim 1 wherein greater than 50% of said dispersing agent by weight is comprised of calcium silicate.
  - 25 6. A flash-melt pharmaceutical dosage form according to claim 1 wherein greater than 80% of said dispersing agent by weight is comprised of calcium silicate.
  7. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate is crystalline.
  - 30 8. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate is amorphous.

9. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate is ortho-, meta- or alpha triclinic-calcium silicate.
10. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate is alpha triclinic-calcium silicate.
11. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate is comprised of a combination of alpha triclinic-calcium silicate and at least one other pharmaceutical grade of calcium silicate wherein said alpha triclinic-calcium silicate comprises from about 10% to about 90% by weight of said combination.
12. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate has a surface area of  $1.0 \text{ m}^2/\text{gm}$  to  $210 \text{ m}^2/\text{gm}$ , bulk density of  $0.075 \text{ g/cc}$  to  $0.90 \text{ g/cc}$ , true density of  $1.70 \text{ g/cc}$  to  $2.90 \text{ g/cc}$  and volatile content of less than 1% to 14% w/w.
13. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate is alpha triclinic calcium silicate that has a surface area of about  $1.3 \text{ m}^2/\text{gm}$ , bulk density of about  $0.63 \text{ g/cc}$ , true density of about  $2.90 \text{ g/cc}$  and volatile content of less than 1% w/w.
14. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate is ortho crystalline calcium silicate that has a surface area of about  $0.98 \text{ m}^2/\text{gm}$ , bulk density of about  $0.492 \text{ g/cc}$ , true density of about  $3.252 \text{ g/cc}$  and volatile content of less than 1% w/w.
15. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate is meta crystalline calcium silicate that has a surface area of about  $2.5 \text{ m}^2/\text{gm}$ , bulk density of about  $0.867 \text{ g/cc}$ , true density of about  $2.940 \text{ g/cc}$  and

volatile content of less than 1% w/w.

5 16. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate is crystalline calcium silicate that has a surface area of about 90.4 m<sup>2</sup>/gm, bulk density of about 0.094 g/cc, true density of about 2.596 g/cc and volatile content of less than 1% w/w.

10 17. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate is amorphous calcium silicate that has a surface area of about 191.3 m<sup>2</sup>/gm, bulk density of about 0.120 g/cc, true density of about 2.314 g/cc and volatile content of about less than 14% w/w.

15 18. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate is amorphous calcium silicate that has a surface area of about 103.0 m<sup>2</sup>/gm, bulk density of about 0.130 g/cc, true density of about 1.702 g/cc and volatile content of about less than 14% w/w.

20 19. A flash-melt pharmaceutical dosage form according to claim 2 wherein said calcium silicate is amorphous calcium silicate that has a surface area of about 209 m<sup>2</sup>/gm, bulk density of about 0.075 g/cc, true density of about 2.035 g/cc and volatile content of about less than 14% w/w.

25 20. A flash-melt pharmaceutical dosage form according to claim 2 wherein said medicament comprises not more than about 30 percent by weight of said medicament based on the total weight of said dosage form.

30 21. A flash-melt pharmaceutical dosage form according to claim 2 wherein said medicament comprises not more than about 15 percent by weight of said medicament based on the total weight of said dosage form.

22. A flash-melt pharmaceutical dosage form according to claim 2 wherein said superdisintegrant agent comprises from about 3 to about 15 percent by weight of said superdisintegrant agent based on the total weight of said dosage form.
- 5 23. A flash-melt pharmaceutical dosage form according to claim 2 wherein said superdisintegrant agent comprises from about 4 to about 10 percent by weight of said superdisintegrant agent based on the total weight of said dosage form.
- 10 24. A flash-melt pharmaceutical dosage form according to claim 2 wherein said superdisintegrant agent comprises from about 4 to about 8 percent by weight of said superdisintegrant agent based on the total weight of said dosage form.
- 15 25. A flash-melt pharmaceutical dosage form according to claim 2 wherein said superdisintegrant agent comprises from about 5 to about 7 percent by weight of said superdisintegrant agent based on the total weight of said dosage form.
- 20 26. A flash-melt pharmaceutical dosage form according to claim 2 wherein said superdisintegrant agent comprises from about 8 to about 12 percent by weight of said superdisintegrant agent based on the total weight of said dosage form.
- 25 27. A flash-melt pharmaceutical dosage form according to claim 2 wherein said superdisintegrant agent comprises from about 9 to about 10 percent by weight of said superdisintegrant agent based on the total weight of said dosage form.
28. A flash-melt pharmaceutical dosage form according to claim 2 wherein said superdisintegrant agent is crospovidone, croscarmellose sodium, sodium starch glycolate, low-substituted hydroxypropyl cellulose or pregelatinized starch.
- 30 29. A flash-melt pharmaceutical dosage form according to claim 2 wherein said superdisintegrant agent is crospovidone or croscarmellose sodium.

30. A flash-melt pharmaceutical dosage form according to claim 29 wherein based on the total weight of said dosage form, said crospovidone comprises from about 6 to about 8 percent by weight of said crospovidone and said croscarmellose sodium comprises from about 2 to about 4 percent by weight of said croscarmellose sodium.

31. A flash-melt pharmaceutical dosage form according to claim 1 further comprising a distributing agent.

32. A flash-melt pharmaceutical dosage form according to claim 31 wherein said distributing agent comprises from about 1 to about 10 percent by weight of said distributing agent based on the total weight of said dosage form.

33. A flash-melt pharmaceutical dosage form according to claim 31 wherein said distributing agent comprises from about 1.5 to about 3 percent by weight of said distributing agent based on the total weight of said dosage form.

34. A flash-melt pharmaceutical dosage form according to claim 31 wherein said distributing agent is amorphous silica, fumed silica, diatomaceous earth, talc, kaolin or magnesium aluminum trisilicate.

35. A flash-melt pharmaceutical dosage form according to claim 31 wherein said distributing agent comprises from about 10 to about 50 percent by weight of said binder based on the total weight of said dosage form.

36. A flash-melt pharmaceutical dosage form according to claim 31 wherein said distributing agent comprises from about 12 to about 20 percent by weight of said binder based on the total weight of said dosage form.

37. A flash-melt pharmaceutical dosage form according to claim 2 wherein said binder is microcrystalline cellulose, hydroxypropyl cellulose, ethyl cellulose,

lactose, mannitol or calcium phosphate.

38. A flash-melt pharmaceutical dosage form comprising a medicament, a superdisintegrant, a dispersing agent and a binder wherein said medicament is aripiprazole and comprises not more than about 30 percent by weight of said medicament based on the total weight of said dosage form, said dispersing agent is calcium silicate having a surface area of  $1.0 \text{ m}^2/\text{gm}$  to  $210 \text{ m}^2/\text{gm}$ , bulk density of  $0.075 \text{ g/cc}$  to  $0.90 \text{ g/cc}$ , true density of  $1.70 \text{ g/cc}$  to  $2.90 \text{ g/cc}$  and volatile content of less than 1% to 14% w/w and which comprises from about 20 to about 70 percent by weight of said dispersing agent based on the total weight of said dosage form, said superdisintegrant is crospovidone, croscarmellose sodium, sodium starch glycolate, low-substituted hydroxypropyl cellulose or pregelatinized starch and which comprises 3 to 15 percent by weight of said superdisintegrant agent based on the total weight of said dosage form.

39. A flash-melt pharmaceutical dosage form comprising a medicament, a superdisintegrant, a dispersing agent, a distributing agent and a binder wherein said medicament is aripiprazole and comprises not more than about 30 percent by weight of said medicament based on the total weight of said dosage form, said dispersing agent is calcium silicate having a surface area of  $1.0 \text{ m}^2/\text{gm}$  to  $210 \text{ m}^2/\text{gm}$ , bulk density of  $0.075 \text{ g/cc}$  to  $0.90 \text{ g/cc}$ , true density of  $1.70 \text{ g/cc}$  to  $2.90 \text{ g/cc}$  and volatile content of less than 1% to 14% w/w and which comprises from about 20 to about 70 percent by weight of said dispersing agent based on the total weight of said dosage form, said superdisintegrant is crospovidone, croscarmellose sodium, sodium starch glycolate, low-substituted hydroxypropyl cellulose or pregelatinized starch and which comprises 3 to 15 percent by weight of said superdisintegrant agent based on the total weight of said dosage form and wherein said distributing agent is is amorphous silica, fumed silica, diatomaceous earth, talc, kaolin or magnesium aluminum trisilicate and comprises from about 10 to about 50 percent by weight of said distributing agent based on the total

weight of said dosage form.

40. A flash-melt pharmaceutical dosage form comprising a medicament, a superdisintegrant, a dispersing agent and a binder wherein said medicament is aripiprazole and comprises not more than about 30 percent by weight of said medicament based on the total weight of said dosage form, said dispersing agent is calcium silicate having a surface area of  $1.0 \text{ m}^2/\text{gm}$  to  $210 \text{ m}^2/\text{gm}$ , bulk density of  $0.075 \text{ g/cc}$  to  $0.90 \text{ g/cc}$ , true density of  $1.70 \text{ g/cc}$  to  $2.90 \text{ g/cc}$  and volatile content of less than 1% to 14% w/w and which comprises from about 35 to about 45 percent by weight of said dispersing agent based on the total weight of said dosage form, said superdisintegrant is crospovidone and croscarmellose sodium, said crospovidone comprises from about 6 to about 8 percent by weight of said crospovidone based on the total weight of said dosage form and said croscarmellose sodium comprises from about 2 to about 4 percent by weight of said croscarmellose sodium based on the total weight of said dosage form.

41. A flash-melt pharmaceutical dosage form comprising a medicament, a superdisintegrant, a dispersing agent and a binder wherein said medicament is aripiprazole and comprises not more than about 30 percent by weight of said medicament based on the total weight of said dosage form, said dispersing agent is calcium silicate having a surface area of  $1.0 \text{ m}^2/\text{gm}$  to  $210 \text{ m}^2/\text{gm}$ , bulk density of  $0.075 \text{ g/cc}$  to  $0.90 \text{ g/cc}$ , true density of  $1.70 \text{ g/cc}$  to  $2.90 \text{ g/cc}$  and volatile content of less than 1% to 14% w/w and which comprises from about 35 to about 45 percent by weight of said dispersing agent based on the total weight of said dosage form, said superdisintegrant is crospovidone and croscarmellose sodium, said crospovidone comprises from about 6 to about 8 percent by weight of said crospovidone based on the total weight of said dosage form and said croscarmellose sodium comprises from about 2 to about 4 percent by weight of said croscarmellose sodium based on the total weight of said dosage form and wherein said distributing agent is is amorphous silica, fumed silica, diatomaceous earth, talc, kaolin or magnesium aluminum trisilicate and comprises from about 1

to about 10 percent by weight of said distributing agent based on the total weight of said dosage form.

42. A flash-melt pharmaceutical dosage form according to claim 40 prepared by dry blending into a mixture, said medicament and said superdisintegrant, said dispersing agent and said binder, compressing said mixture through a suitable compactor or slugger to form compacts or slugs, passing said compacts or slugs through a screen to form granules and compressing said granules to form said flash-melt pharmaceutical dosage form.

43. A flash-melt pharmaceutical dosage form comprising a medicament, a superdisintegrant, a dispersing agent, a distributing agent and a binder wherein said medicament is aripiprazole and comprises not more than about 30 percent by weight of said medicament based on the total weight of said dosage form, said dispersing agent is calcium silicate having a surface area of 1.0 m<sup>2</sup>/gm to 210 m<sup>2</sup>/gm, bulk density of 0.075 g/cc to 0.90 g/cc, true density of 1.70 g/cc to 2.90 g/cc and volatile content of less than 1% to 14% w/w and which comprises from about 20 to about 70 percent by weight of said dispersing agent based on the total weight of said dosage form, said superdisintegrant is crospovidone and croscarmellose sodium and wherein said crospovidone comprises 5 to 8 percent by weight of said crospovidone based on the total weight of said dosage form and wherein said croscarmellose comprises 1 to 4 percent by weight of said crospovidone based on the total weight of said dosage form, and wherein said distributing agent is is amorphous silica, fumed silica, diatomaceous earth, talc, kaolin or magnesium aluminum trisilicate and comprises from about 10 to about 50 percent by weight of said distributing agent based on the total weight of said dosage form.

44. A flash-melt pharmaceutical dosage form comprising a medicament, a superdisintegrant, a dispersing agent, a distributing agent and a binder wherein said medicament is aripiprazole and comprises not more than about 30 percent by



weight of said medicament based on the total weight of said dosage form, said dispersing agent is calcium silicate having a surface area of 1.0 m<sup>2</sup>/gm to 210 m<sup>2</sup>/gm, bulk density of 0.075 g/cc to 0.90 g/cc, true density of 1.70 g/cc to 2.90 g/cc and volatile content of less than 1% to 14% w/w and which comprises from about 20 to about 70 percent by weight of said dispersing agent based on the total weight of said dosage form, said superdisintegrant is crospovidone and croscarmellose sodium and wherein said crospovidone comprises about 7 percent by weight of said crospovidone based on the total weight of said dosage form and wherein said croscarmellose comprises about 3 percent by weight of said crospovidone based on the total weight of said dosage form, and wherein said distributing agent is is amorphous silica, fumed silica, diatomaceous earth, talc, kaolin or magnesium aluminum trisilicate and comprises from about 10 to about 50 percent by weight of said distributing agent based on the total weight of said dosage form.

45. A flash-melt pharmaceutical dosage form comprising a medicament, a superdisintegrant, a dispersing agent, a distributing agent and a binder wherein said medicament is aripiprazole and comprises not more than about 30 percent by weight of said medicament based on the total weight of said dosage form, said dispersing agent is calcium silicate having a surface area of 1.0 m<sup>2</sup>/gm to 210 m<sup>2</sup>/gm, bulk density of 0.075 g/cc to 0.90 g/cc, true density of 1.70 g/cc to 2.90 g/cc and volatile content of less than 1% to 14% w/w and which comprises from about 35 to about 45 percent by weight of said dispersing agent based on the total weight of said dosage form, said superdisintegrant is crospovidone and croscarmellose sodium and wherein said crospovidone comprises about 7 percent by weight of said crospovidone based on the total weight of said dosage form and wherein said croscarmellose comprises about 3 percent by weight of said crospovidone based on the total weight of said dosage form, and wherein said distributing agent is is amorphous silica, fumed silica, diatomaceous earth, talc, kaolin or magnesium aluminum trisilicate and comprises from about 10 to about 50 percent by weight of said distributing agent based on the total weight of said

dosage form.

46. A flash-melt pharmaceutical dosage form comprising a medicament, a superdisintegrant, a dispersing agent, a distributing agent and a binder wherein said medicament is aripiprazole and comprises not more than about 20 percent by weight of said medicament based on the total weight of said dosage form, said dispersing agent is calcium silicate having a surface area of  $1.0 \text{ m}^2/\text{gm}$  to  $210 \text{ m}^2/\text{gm}$ , bulk density of  $0.075 \text{ g/cc}$  to  $0.90 \text{ g/cc}$ , true density of  $1.70 \text{ g/cc}$  to  $2.90 \text{ g/cc}$  and volatile content of less than 1% to 14% w/w and which comprises from about 35 to about 45 percent by weight of said dispersing agent based on the total weight of said dosage form, said superdisintegrant is crospovidone and croscarmellose sodium and wherein said crospovidone comprises about 7 percent by weight of said crospovidone based on the total weight of said dosage form and wherein said croscarmellose comprises about 3 percent by weight of said crospovidone based on the total weight of said dosage form, and wherein said distributing agent is is amorphous silica, fumed silica, diatomaceous earth, talc, kaolin or magnesium aluminum trisilicate and comprises from about 10 to about 50 percent by weight of said distributing agent based on the total weight of said dosage form.

47. A flash-melt pharmaceutical dosage form comprising a medicament, a superdisintegrant, a dispersing agent, a distributing agent and a binder wherein said medicament is aripiprazole and comprises not more than about 10 percent by weight of said medicament based on the total weight of said dosage form, said dispersing agent is calcium silicate having a surface area of  $1.0 \text{ m}^2/\text{gm}$  to  $210 \text{ m}^2/\text{gm}$ , bulk density of  $0.075 \text{ g/cc}$  to  $0.90 \text{ g/cc}$ , true density of  $1.70 \text{ g/cc}$  to  $2.90 \text{ g/cc}$  and volatile content of less than 1% to 14% w/w and which comprises from about 35 to about 45 percent by weight of said dispersing agent based on the total weight of said dosage form, said superdisintegrant is crospovidone and croscarmellose sodium and wherein said crospovidone comprises about 7 percent by weight of said crospovidone based on the total weight of said dosage form and

wherein said croscaremellose comprises about 3 percent by weight of said crospovidone based on the total weight of said dosage form.

48. A flash-melt pharmaceutical dosage form comprising a medicament, a superdisintegrant, a dispersing agent, a distributing agent and a binder wherein said medicament is aripiprazole and comprises not more than about 5 percent by weight of said medicament based on the total weight of said dosage form, said dispersing agent is calcium silicate having a surface area of 1.0 m<sup>2</sup>/gm to 210 m<sup>2</sup>/gm, bulk density of 0.075 g/cc to 0.90 g/cc, true density of 1.70 g/cc to 2.90 g/cc and volatile content of less than 1% to 14% w/w and which comprises from about 35 to about 45 percent by weight of said dispersing agent based on the total weight of said dosage form, said superdisintegrant is crospovidone and croscarmellose sodium and wherein said crospovidone comprises about 7 percent by weight of said crospovidone based on the total weight of said dosage form and wherein said croscaremellose comprises about 3 percent by weight of said crospovidone based on the total weight of said dosage form.